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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/764,581

Applicant(s)

SAKANYAN ET AL.

Examiner

Jennifer Dunston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 28-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 11-16, 28, 30, 32, 33 and 40 is/are allowed.
- 6) ☒ Claim(s) 1, 10, 36 and 38 is/are rejected.
- 7) ☒ Claim(s) 2-8, 29, 31, 34, 35, 37 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This action is in response to the amendment, filed 11/28/2005, in which claims 17-27 were canceled; claims 1-4, 6-11, 14 and 16 were amended; and claims 28-40 were newly added. Currently, claims 1-16 and 28-40 are pending. Applicants' arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn. **This action is FINAL.**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant elected Group I (claims 1-16) without traverse in the reply filed on 5/9/2005. New claims 28-40 read on the invention of Group I. Currently, claims 1-16 and 28-40 are under consideration.

Claim Objections

Claim 31 is objected to because of the following informalities: the word order of the claim should be improved. The phrase "at position nucleotide -89" should be changed to "nucleotide at position -89." This is a new objection, necessitated by the addition of new claim 31. Appropriate correction is required.

Claim 38 objected to because of the following informalities: a space should be inserted between the terms "K12" and "A19" to be consistent with the strain designation provided in

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Table 1 of the present specification. This is a new objection, necessitated by the addition of new claim 38. Appropriate correction is required.

Response to Arguments

The previous objections of claims 1, 8, 9 and 14 have been withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 112

Claim 10 recites the limitation "said added RNA polymerase" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 10 depends from claim 9, which has been amended to delete the phrase "optionally, adding a thermostable RNA polymerase." This limitation is now found in claim 28. It would be remedial to amend claim 10 to depend from claim 28. This is a new rejection, necessitated by Applicant's amendment to the claims filed 11/28/2005.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and/or use the invention. This is a new rejection, necessitated by Applicant's amendment of the claims to add claim 38.

Claim 38 is drawn to or encompass the use of bacterial cell-free extracts obtained from *E. coli* K12 A19 cells having a *rna19 gdhA2 his-95 relA1 spoT1 metB1* genotype.

The application discloses *E. coli* K12 A19 cells that are encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in

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the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description. A statement that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon granting of a patent is also required.

Response to Arguments

The previous rejection of claims 1-8, 11 and 14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

Claims 1 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowrin et al (FEMS Microbiology Letters, Vol. 115, pages 1-6, 1994; see the entire reference) as evidenced by Inouye et al (Nucleic Acids Research, Vol. 13, No. 9, pages 3101-3110, 1985; see the entire reference). This rejection was made in the Office action mailed 7/26/2005 and is maintained for reasons of record in the previous office action, which are extended to new claim 36 and repeated below.

Bowrin et al teach a method for *in vitro* transcription, comprising the steps of (i) providing a cell-free transcription system, wherein the concentration of the alpha subunit of RNA polymerase is increased relative to the other subunits of the RNA polymerase, and (ii) recovering

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the synthesized RNA transcript (e.g. pages 2-3, *In vitro transcription assays*; pages 4-5, *Effect of α subunit on cell-free ompF transcription*; Figure 5). Bowrin et al teach that the cell-free system is capable of enabling RNA synthesis from a DNA template comprising an *lpp* promoter (e.g. Figure 5). The teachings of Bowrin et al read on the claimed invention because the *lpp* promoter inherently contains an UP element (Inouye et al, e.g. Figure 1). As disclosed in the instant specification, the UP element is an AT-rich sequence located upstream at the -35 site of strong promoters (e.g. page 3, lines 15-20). The -35 region of the *lpp* promoter contains an AT-rich region (Inouye et al, e.g. Figure 1). Thus, the cell-free system of Bowrin et al enables transcription from a DNA template comprising a promoter with at least one UP element.

Response to Arguments

Applicant's arguments filed 11/28/2005 have been fully considered but they are not persuasive. The response essentially asserts that Bowrin et al does not teach an increase in the 140 bp *lpp* transcript in the presence of RNA polymerase subunit alpha, and thus the reference does not disclose the claimed method.

If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). In the instant case, the claimed method steps fully define the claimed method, and these method

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steps are taught by Bowrin et al. The claimed method steps do not refer to increasing RNA synthesis. Thus, claim 1 is anticipated by the teachings of Bowrin et al.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Response to Arguments - 35 USC § 103

The rejection of claims 1, 2, 6, 7 and 9-14 under 35 U.S.C. 103(a) as being unpatentable over Lesley et al in view of Bowrin et al as evidenced by Bowrin, Brissette and Inouye has been withdrawn in view of Applicant's amendment. The claims have been amended to include the step of adding a DNA template comprising a strong bacterial promoter with at least one UP element. The *OmpF* promoter of plasmid PKI0033 does not contain an UP element. Furthermore, it would not be obvious to modify the method of Lesley et al to include only a control plasmid comprising a promoter that contains an UP element.

The rejection of claims 1-3, 6, 7 and 9-14 under 35 U.S.C. 103(a) as being unpatentable over Lesley et al in view of Bowrin et al) and Savchenko et al as evidenced by Bowrin, Brissette and Inouye has been withdrawn in view of Applicant's amendment. The claims have been amended to include the step of adding a DNA template comprising a strong bacterial promoter with at least one UP element. The *OmpF* promoter of plasmid PKI0033 does not contain an UP element. Furthermore, it would not be obvious to modify the method of Lesley et al to include only a control plasmid comprising a promoter that contains an UP element.

The rejection of claims 1, 2, 4-7 and 9-14 under 35 U.S.C. 103(a) as being unpatentable over Lesley et al in view of Bowrin et al and Xue et al as evidenced by Bowrin, Brissette and

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Inouye has been withdrawn in view of Applicant's amendment. The claims have been amended to include the step of adding a DNA template comprising a strong bacterial promoter with at least one UP element. The *OmpF* promoter of plasmid PKI0033 does not contain an UP element. Furthermore, it would not be obvious to modify the method of Lesley et al to include only a control plasmid comprising a promoter that contains an UP element.

The rejection of claims 1, 2, 6, 7 and 9-16 under 35 U.S.C. 103(a) as being unpatentable over Lesley et al in view of Bowrin et al and Uptain et al as evidenced by Bowrin, Brissette and Inouye has been withdrawn in view of Applicant's amendment. The claims have been amended to include the step of adding a DNA template comprising a strong bacterial promoter with at least one UP element. The *OmpF* promoter of plasmid PKI0033 does not contain an UP element. Furthermore, it would not be obvious to modify the method of Lesley et al to include only a control plasmid comprising a promoter that contains an UP element.

Conclusion

Claims 2-8, 29, 34, 35, 37 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 9, 11-16, 28, 30, 32, 33 and 40 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, <http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with,

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the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston
Examiner
Art Unit 1636

jad

CELIAN QIAN
PATENT EXAMINER



SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).
5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.